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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/164,764	10/01/1998	DAVID SIDRANSKY	01107.76459	7055

7590 05/16/2002

BANNER & WITCOFF, LTD.  
1001 G STREET, N.W.  
11TH FL.  
WASHINGTON, DC 20001

EXAMINER

SOUAYA, JEHANNE E

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/16/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**Application No.  
**09/164,764**Applicant(s)  
**Sidransky**Examiner  
**Jehanne Souaya**Art Unit  
**1634**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED May 3, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**THE PERIOD FOR REPLY [check only a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attachment

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: 23, 29-32, 35, 36, 39-41, and 43-45
- Claim(s) objected to: \_\_\_\_\_
- Claim(s) rejected: 24-28, 34, 37, 38, and 42
- Claim(s) withdrawn from consideration: \_\_\_\_\_
8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

### *Attachment*

The after final amendment filed May 3, 2002 will not be entered because the proposed amendment raises new issues requiring further search and consideration. Specifically, the proposed amendment to claim 34, from "histopathological margin specimen" to "comprising tumor margin" requires further search and consideration.


All rejections made of record in the final rejection mailed 2/4/2002 are maintained for reasons made of record in previous office actions. With regard to applicants traversal of the rejection made under 35 USC 103 of instantly pending claims 24-28 and 37-38, the response asserts that the combined reference do not teach a method with a step of identifying a cancer in the organ which drains in the body fluid. This argument has been thoroughly reviewed but was not found persuasive because all organs drain blood and the claims do not specify any organs in particular, thus the teachings of Brugieres satisfy the claim limitations. The response further traverses that Brugieres teaches testing whole blood samples and thus teaches the identification of mutations that are found in all cells of an individual. This argument has been thoroughly reviewed but was not found persuasive as the claims are not drawn to a specific type of blood sample nor do the claims contain the limitation of testing for only non-germ line mutations. The response further asserts that in the teachings of Brugieres, no tumor is present. This argument has been thoroughly reviewed but was not found persuasive as Brugieres teaches screening mutations in subjects with malignant tumors (see abstract, second sentence, p. 453, col. 1, 2nd full paragraph). The response also asserts that none of the teachings of Gonzalez-Zulueta or Merlo or Ah-See teach identification of a cancer by determining microsatellite repeat polymorphisms in a body fluid which drains an organ. This argument has been thoroughly

reviewed but was found unpersuasive as the rejection above sets forth that the teachings of Gonzalez-Zulueta and Merlo and Ah-See were cited to show that it was known at the time of the invention that microsatellite repeat polymorphisms were detected in specific types of cancer. Applicants arguments regarding the teachings of Gonzalez-Zulueta and Merlo and Ah-See appear to be directed to the fact that each reference does not teaching every limitation in the claim. However, the references were not cited in a rejection based on 35 USC 102 but on 35 USC 103(a). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For these reasons, and the reasons made of record previously, the rejection is maintained.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Jehanne Souaya  
Patent examiner  
Art Unit 1634

May 13, 2002

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600